



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/671,995 | 09/26/2003 | Richard G. Woodbury | | 3882 |

7590 11/05/2007
Lisa A. Haile, J.D., Ph.D
DLA PIPER RUDNICK GRAY CARY US LLP
4365 Executive Drive
Suite 1100
San Diego, CA 92121-2133

EXAMINER

MARVICH, MARIA

ART UNIT PAPER NUMBER

1633

MAIL DATE DELIVERY MODE

11/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|--|--|
| Office Action Summary | Application No. 10/671,995 | Applicant(s) WOODBURY ET AL. | |
| | Examiner Maria B. Marvich, PhD | Art Unit 1633 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29, 32, 33 and 35-47 is/are pending in the application.
- 4a) Of the above claim(s) 2-25, 36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 26-29, 32, 33, 35 and 38-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1633

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/17/07 has been entered.

Claim Objections

Claims 1, 26 and 39 are objected to because of the following informalities: It is noted in claim 1 that recitation of "an amino acid sequence as set forth in SEQ ID NO:17" does not limit the domain to the sequence of SEQ ID NO:17 but simply indicates that "an amino acid" dipeptide at the minimum must be included. It would be remedial to recite --the amino acids sequence--.

In claim 26, the word --is-- is missing between the words "domain 2" and "streptavidin".

Claim 39 is objected to because of the following informalities: the recitations of "polyhistidine", "V5 epitope" and "FLAG epitope" should be preceded by articles such as --a--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1633

Claims 1, 26, 32-35, 38, 39 and 45-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 has been amended to encompass a fusion protein comprising "at least three domains configured as domain 1-GBP domain-domain 2". A reasonable interpretation of the recitation of "at least three domains configured" is of a fusion protein comprising at least three multimers of a "domain 1-GBP-domain 2" unit. The examiner has been unable to find support in the originally filed specification for such a configuration. Rather, the specification is directed to plasmids comprising a GBP fusion protein in which the fusion protein comprises 1-7 GBP domains with on one or both sides by binding proteins and affinity tag proteins. This does not overlap with a configuration of repeating units of a unit of domain 1- GBP- domain 2. Therefore, the added limitation is impermissible NEW MATTER.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 27-29 and 45-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1633

Claim 1 is vague and indefinite in that the metes and bounds of “at least three domains configured as domain 1- GBP-domain 2” in view of claims 27-29 and 40-44 are unclear. A reasonable interpretation of the recitation of “at least three domains configured” is of a fusion protein comprising three multimers of a “domain 1-GBP-domain 2” unit. The limitation in claims 27, 28 and 29 that domain 1 and 2 are separated by 2-7 GBP domains, cannot occur as the resulting fusion would not be configured as domain 1-GBP-domain 2. As well, claims 40-44 drawn to SEQ ID NO:s 6, 8, 10, 12 and 16 are drawn to fusions comprising 7 or 15 (SEQ ID NO:16) fusion peptides that do not meet the requirement of “at least three domains configured as domain 1- GBP-domain 2”.

Conclusion

No claims allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

Art Unit: 1633

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Maria B Marvich, PhD
Examiner
Art Unit 1633